

## **REMARKS**

Favorable reconsideration is respectfully requested in view of the following remarks.

### **I. CLAIM STATUS**

In items 4 and 6 on page 1 and in the obviousness rejection on pages 2-3 of the Office Action, claims 2, 3 and 14-16 are incorrectly listed as the pending and rejected claims.

Kindly note that claims 2-16 are pending and claims 2-5 and 14-16 are rejected. Claims 6-13 were withdrawn (not canceled) as non-elected subject matter. Please clarify the status of the pending and rejected claims.

### **II. OBVIOUSNESS REJECTION**

On pages 2-3, claims 2-3 [sic, 2-5] and 14-16 were newly rejected under 35 USC § 103(a) as obvious over EP 0162,303 (sic, EP 0162,302, cited in the IDS of October 2, 1998) or the characterization of JP 6-505342 and JP 232855 [sic, 4-232855] in NPL document "Dispatch 116024" (cited in the IDS of June 9, 2005).

This rejection is respectfully traversed.

To establish obviousness, three criteria must be met. First, the prior art references must teach or suggest each and every element of the claimed invention. M.P.E.P. § 2143.03. Second, there must be some suggestion or motivation in the references to either modify or combine the reference teachings to arrive at the claimed invention. M.P.E.P. § 2143.01. Third, the prior art must provide a reasonable expectation of success. M.P.E.P. § 2143.02.

On page 2 of the Office, the Examiner stated:

EP 162,302 teaches a multilayer analytical element comprising a colorimetric reagent, polymer beads embedded with the claimed light reflective particles and a hydrophilic matrix supporting the reagents and beads.

The characterization of JP 6-505342 and JP 232855 in NPL document 'Dispatch 116024' teaches a multilayer analytical element comprising a colorimetric reagent,

polymer beads embedded with the claimed light reflective particles and a hydrophilic matrix supporting the reagents and beads.

Contrary to this position, the polymer beads containing embedded light reflective particles as in the claims of the present application are not described nor suggested by any of the cited references.

As discussed in the response filed on April 27, 1999, EP 162,302 is silent about the polymer beads containing embedded light reflective particles. Instead, EP 162,302 discloses an invention related to an integral multilayer analytical element. At page 8, line 8 to page 9, line 20 of EP 162,302, there is a description about an analytical element which has a light-shielding layer in which light-shielding microparticles or light-shielding and light-reflecting microparticles (hereinafter referred to as "lightshielding particles") are dispersed in a small amount of a film-forming hydrophilic polymer binder. From this description, it is clear that the light-shielding particles are dispersed in the form of the particles *per se* in the hydrophilic polymer film. It is respectfully submitted that this is not the same as, nor a suggestion for, polymer beads containing embedded light reflective particles as claimed.

The characterization of the publications JP 6505342 and JP 4-232855 in NPL document 'Dispatch 116024' (The Japanese Patent Office's communication action mailed March 29, 2005) describes nothing about the polymer beads containing embedded light reflective particles. In fact, none of the publications JP 6505342 and JP 4-232855 disclose polymer beads containing embedded light reflective particles.

Thus, none of the cited references disclose or suggest the use of polymer beads containing embedded light reflective particles as claimed. For this reason, the cited prior art references fail to render obvious the claimed invention, because the references fail to teach or suggest each and every element of the claimed invention.

Furthermore, the claimed test device is believed to be patentable over the cited references in view of the unexpected results discussed below.

As discussed in the response filed on December 10, 2002, the use of the polymer beads containing embedded light reflective particles exhibits unexpected results.

When the light reflective particles are directly contained in the reagent layer (as in the prior art), there is the following problem in practical use as described on page 2, line 25 to page 4, line 1 of the present specification. Conventionally, in this kind of dry measuring test device for determining a substance to be measured in a liquid sample through the coloring reaction between the substance to be measured and the reagent, in order to enhance measurement accuracy, an attempt was made to have the light reflective particles directly contained in the reagent layer and have the reagent for coloring contained therein as well. However, if a large amount of light reflective particles is contained to improve the measurement accuracy, the reagent layer becomes so dense that a liquid sample can hardly penetrate and develop, and it takes a long time until the amount of the coloring matter generated by the reaction with the reagent becomes sufficiently measurable. Thus, this is a problem in practical use. Further, it is disadvantageous in that the measurement accuracy may possibly be lowered due to dryness if the measuring time is prolonged as described above.

This problem is solved by the present invention by allowing the light reflective particles to be embedded in polymer beads. The advantages of embedding light reflective particles in polymer beads are clearly evidenced by Example 1 and Comparative Example 1 (see pages 19-22) in the present specification. The results from these examples demonstrate that for the test device of the present invention (Example 1) the sample liquid permeated the reagent layer well and the reaction rate between the reagent and the substance to be measured was higher than that of conventional dry measuring test device (Comparative Example 1). See lines 1-13 on page 22 of the disclosure.

Again, none of the cited prior art references disclose or suggest the use of polymer beads containing embedded light reflective particles as claimed. Thus, the advantages (unexpected results) of using polymer beads containing embedded light reflective particles is not suggested by

the cited references. This is further evidence of the non-obviousness of the present invention. For these reasons, the cited prior art references do not establish obviousness.

In view of the above, the obviousness rejection of claims 2-5 and 14-16 over EP 0162,302 or the characterization of JP 6-505342 and JP 4-232855 in NPL document "Dispatch 116024" is untenable and should be withdrawn.

### **III. JAPANESE PRINTED PUBLICATION 9716720 (WO 97/16720)**

On pages 3-4 of the Office Action, it was indicated that the Examiner is aware of a related Japanese printed publication 9716720 (WO 97/16720), that presumably contains the same subject matter as the Fukuoka references and has a publication date of May 9, 1997. A prior art rejection utilizing this reference was not made, because the Examiner was waiting for an English translation thereof. To expedite prosecution, it was suggested that Applicants file a certified translation of the priority documents.

The Office's position regarding WO 97/16720 is respectfully traversed.

WO 97/16720 is a counterpart of the "Fukuoka et al." documents (Fukuoka et al., 2003/0166295, Fukuoka et al., 2003/0175985, Fukuoka et al., 2003/180183 or Fukuoka et al., U.S. 6,777,243) cited on page 3 of the Office Action of February 2, 2005.

As discussed above, the test device of the present invention requires polymer beads containing embedded light reflective particles.

On page 3 of the Office Action of February 2, 2005, the Examiner stated that: "Fukuoka et al. (2003/0166295), Fukuoka et al. (2003/0175985), Fukuoka et al. (2003/180183) and Fukuoka et al. (USP 6,777,243) all teach the polymer beads and titanium dioxide in paragraphs [0254], [0256], [0254] and column 37 lines 40+."

However, as argued in the response of June 2, 2005, these Fukuoka applications (and WO 97/16720, which is a counterpart of the "Fukuoka et al." documents) merely list polymer beads and titanium dioxide as examples of granular substances which may constitute the support of the

device disclosed by the cited applications. It is respectfully submitted that this is not a suggestion to use polymer beads containing embedded light reflective particles. Furthermore, as discussed above, the use of the polymer beads containing embedded light reflective particles exhibits unexpected results.

No where do the Fukuoka applications (and WO 97/16720) disclose or suggest polymer beads containing embedded light reflective particles. The use of the polymer beads containing embedded light reflective particles and its advantages are not suggested by any of the cited applications. For these reasons, a prior art rejection utilizing WO 97/16720 should not be applied.

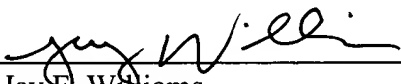
Nonetheless, to expedite prosecution, attached herewith are verified translations of the priority documents (Japanese Patent Application No. 8-290226 and Japanese Patent Application No. 8-290227, both filed on October 31, 1996) as suggested by the Examiner. Accordingly, the instant application, which claims priority to these documents, is entitled to the October 31, 1996 priority date, which precedes the May 9, 1997 publication date for WO 97/16720. For this reason, WO 97/16720 should not be applied in a prior art rejection.

**CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,  
Yoshihiko HIGUCHI et al.

By:   
Jay P. Williams  
Registration No. 48,036  
*for*  
Warren M. Cheek, Jr.  
Registration No. 33,367  
Attorneys for Applicants

WMC/JFW/akl  
Washington, D.C. 20006-1021  
Telephone (202) 721-8200  
Facsimile (202) 721-8250  
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**ATTACHMENTS**

1. Verified English translation of Japanese Application No. 8-290226; and
2. Verified English translation of Japanese Application No. 8-290227.